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Section 5 -510(k) Summary

1 Manufacturing Establishment and Contact Information

MAR - 6 2012

1.1 Manufacturer Name and Address:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730

1.2 Establishment Registration Number:

1221300

1.3 Name, Title, and Telephone Number of Contact:

Name: Eileen M. Boyle
Title: Regulatory Affairs Specialist II
Phone: (781) 999-7781
Fax : (866) 652-8674
eileen.boyle@hologic.com

2 Device Identification

2.1 Device Trade Name:

Hologic Visceral Fat Software

2.2 Common / Usual Name:

Software for Bone Densitometers

2.3 Proposed Intended Use:

The Hologic Visceral Fat Software used on Hologic Discovery bone densitometer total body scans estimates the visceral adipose tissue (visceral fat) content within the android region in an adult male or female population, excluding pregnant women. The content that is estimated is the Visceral Fat Area, Visceral Fat Mass, and Visceral Fat Volume. These values can be displayed in user-defined statistical formats and trends.

The estimated visceral fat content is useful to health care professionals in their management of diseases/conditions where the disease/condition itself, or its treatment can affect the relative amounts of visceral fat content in the android region. The Hologic Visceral Fat software does not diagnose disease, or recommend treatment regimens, or quantify treatment effectiveness. Only the health care professional can make these judgments. Some of the diseases, conditions for which visceral fat estimation is useful include hypertension, impaired fasting glucose, impaired glucose tolerance, diabetes mellitus, dyslipidemia, and metabolic syndrome.

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3 Device Classification

3.1 Classification:

Class II

3.2 Classification Name and Rule

Bone Densitometer: 21 CFR 892.1170

3.3 Classification Panel

Radiology

3.4 Product Code

90 KGI

3.5 Predicate Devices

- 510(k) No.: K103730
  Trade Name: GE Lunar Visceral Fat Software
  SE Date: 5/6/2011
  Manufacturer: GE Medical Systems Lunar

- 510(k) No.: K103265
  Trade Name: Hologic NHANES Whole Body DXA Reference Database
  SE Date: 3/16/2011
  Manufacturer: Hologic, Inc.

4 Device Description

The proposed Hologic® Visceral Fat Software provides an estimate of a patient's visceral fat in the abdominal region of a whole body scan. The results are included in the Adipose Indices section of the Hologic Discovery bone densitometer's body composition report.

5 Performance Testing

Testing was successfully conducted and demonstrates that the Hologic Visceral Fat Software meets all of its functional requirements and performance specifications.

5 Substantial Equivalence

The Hologic® Visceral Fat Software is substantially equivalent to commercially available devices used for the estimation of a patient's visceral fat. The predicate devices selected for comparison are the GE Lunar Visceral Fat Software Option (K103730) and the Hologic NHANES Whole Body DXA Reference Database (K103265). The predicate devices provide substantially equivalent or the same intended use, features and functions as the proposed device.

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6 Conclusion:

The Hologic Visceral Fat Software is an extension of the cleared Discovery NHANES Whole Body DXA Reference Database (K103265). The features and functions are substantially equivalent to those of the indicated commercially distributed device (GE Lunar Visceral Fat Software K103730) with regard to intended use, performance, safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Eileen M. Boyle
Regulatory Affairs Specialist II
Hologic, Inc.
35 Crosby Drive
BEDFORD MA 01730

MAR - 6 2012

Re: K113356
Trade/Device Name: Hologic Visceral Fat Software
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: February 29, 2012
Received: March 1, 2012

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K113356

Device Name:

The Hologic Visceral Fat Software used on Hologic Discovery bone densitometer total body scans estimates the visceral adipose tissue (visceral fat) content within the android region in an adult male or female population, excluding pregnant women. The content that is estimated is the Visceral Fat Area, Visceral Fat Mass, and Visceral Fat Volume. These values can be displayed in user-defined statistical formats and trends.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113356